Claims 27-46 have been cancelled without prejudice. Claims 49-60 are respectfully submitted in order to define certain embodiments of the invention. Claim 49 finds basis in the Specification at page 2, line 22-23, page 3, l. 22-29, page 4, l. 16-18 and page 5, l. 13-15. Claim 50 finds basis in the Specification at page 4, l. 22. Claim 51 finds basis in the Specification at page 4, line 5-7. Claim 52 finds basis in the Specification at page 12, l. 21- page 13, l. 16 and page 18, l. 1-5. Claim 53 finds basis in the Specification at page 4, l. 22, page 4, l. 5-7 and page 12, l. 21- page 13, l. 16. Claim 54 finds basis in the Specification at page 4, l. 22. Claim 55 finds basis in the Specification at page 12, l. 7. Claim 56 finds basis in the Specification at page 18, l. 3. Claim 57 finds basis in the Specification at page 4, l. 5-7, page 4, l. 22, page 12, l. 21- page 13, l. 16, and page 18, l. 4. Claim 58 finds basis in the Specification at page 12, l. 15. Claim 59 finds basis in the Specification at page 12, l. 7. Claim 60 finds basis in the Specification at page 18, l. 1-5.

The Office Action of December 18, 2002 rejected claims 27, 30-34 and 38-46 under 35 U.S.C. 102(b) as being anticipated by Hughes et al. U.S. Patent No. 5,322,689. Applicants have canceled these claims without prejudice and respectfully submit that this rejection is now moot as to the claims remaining in this application. Reconsideration of this rejection and consideration of new claims 49-60 is therefore respectfully requested.

The Office Action of December 18, 2002 further rejected claims 27 and 30-46 under 35 U.S.C. 102(b) as being anticipated by Simon et al. U.S. Patent No. 5,730,972. Applicants have canceled these claims without prejudice and respectfully submit that this rejection is now moot as to the claims remaining in this application. Reconsideration of this rejection and consideration of new claims 49-60 is therefore respectfully requested.

Claims 27-46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Froix et al. U.S. Patent No. 5,851,538 in view of Simon et al. U.S. Patent No. 5,730,972. Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims and the ensuing discussion. Applicants respectfully note that claims 27-46 have been canceled without prejudice and therefore claims 49-60 will be the subject of the ensuing discussion.

Froix et al. relates to retinoid compositions wherein the retinoids are encapsulated or trapped in microporous spheres:

> The particles are ***solid, water-insoluble particles***, microscopic in size, with a continuous network of pores open to the exterior of the particles, and the particle material is chemically inert with respect to the retinoids and any other ingredients... [Froix, et al., col. 1, l. 41-49] (emphasis added)

Applicants respectfully point out that the crosslinked polymers of esters of acrylic or methacrylic acid are quite distinct from the water-soluble acrylate polymers useful in the compositions and methods of applicants' invention. Furthermore, nowhere does Froix et al. suggest or describe using sugars in retinoid-containing compositions in order to mitigate retinoid irritation.

Simon et al. does not compensate for the insufficiencies of Froix et al. in leading one of ordinary skill in the art to the compositions and methods of applicants' invention. Simon et al. relates to a composition for combating skin marks and/or aging of the skin containing a saccharide ester of ascorbic acid and a water-soluble sulphonic UVA screening agent. [Simon et al., Abstract]

Simon et al. provides compositions that combat skin marks and/or aging of the skin by the use of UVA-screening agents in conjunction with free radical scavengers. One of ordinary skill in the art would not have looked to the sunscreen formulation art to find compositions that would enhance the penetration of retinoids into the skin—not only do such UVA-screening agents function by resting on the exterior body and absorbing the ultraviolet light before it enters the skin, they have ***no*** function ***within*** the skin matrix. Therefore, the Simon et al. compositions would not have been expected to have enhanced permeation characteristics.

Furthermore, nowhere does Simon et al. indicate the use of retinoids or lipophilic ingredients in the described compositions. Rather, Simon et al. utilizes water-soluble UVA-screening agents. In contrast, certain embodiments of the compositions of applicants' invention utilize a hydrophobic active agent such as retinoids or other vitamins. Thus, Simon et al. does not contemplate the enhanced permeation of lipophilic compounds achieved with the compositions of applicants' invention. While sunscreens may be added to the compositions of applicants' invention for sun protection, the components are not intended to enhance permeation of sunscreens into the skin—this is actually undesirable. Simon et al. neither describes nor suggests the topical permeation-enhancing compositions of applicants' invention. That the hydrophilic polymers and sugars of applicants' compositions enhance permeation of lipophilic vitamins and assist in mitigating irritation is quite surprising in view of Simon et al.

Simon et al. does not discuss enhanced delivery—it merely states that the saccharide derivatives are compatible with UVA screens. Ability to place the saccharide in the same formulation as a UVA sunscreen is not tantamount to enhancing the penetration of either the UVA sunscreen or the saccharide to the skin.

Applicants respectfully submit that penetration enhancement and irritation mitigation are unexpectedly and surprisingly enhanced using the compositions of applicants' invention. Applicants respectfully direct the attention of the Patent and Trademark Office to the results set forth in Tables 1 and 2 of the Specification of the above-captioned patent application. Composition B, containing only retinol and Acrylates/C10-30 alkyl Acrylate cross polymer effects a delivery of 0.642% retinol, enhancing retinol delivery by a factor of about 3.67 compared with Composition A, containing a conventional emulsifier. Composition C, containing only retinol and ascorbic acid-2-glucoside and a conventional emulsifier, effects a delivery of 0.241% retinol, enhancing retinol delivery by a factor of about 1.38 compared with Composition A. However, unexpectedly, Composition D, containing both Acrylates/C10-30 alkyl Acrylate cross polymer and ascorbic acid-2-glucoside effects a delivery of 1.25%, or delivery enhancement of a factor of 7.20. This is a surprisingly increased enhancement of retinol delivery.

Thus, applicants respectfully contend that nothing in the Froix et al. patent would have motivated one of ordinary skill in the art to combine such compositions with those of Simon et al. to arrive at the compositions of applicants' invention. Although applicants respectfully submit that the rejections under 35 U.S.C. 103(a) are moot in view of the foregoing amendments to the claims, consideration of new claims 49-60 in view of the foregoing discussion is respectfully requested.

In view of the foregoing discussion and amendments to the claims, applicants respectfully request reconsideration of the rejections set forth in the Office Action of December 18, 2002 and respectfully request consideration of the new claims. An early allowance is earnestly solicited.

Respectfully submitted,

Andrea L. Colby
Attorney for Applicants
Reg. No. 30,194

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
May 19, 2003